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APPLICATION NUMBER: *60/545,161*
FILING DATE: *February 18, 2004*

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Attorney Docket No. 39348-200945

17224 U.S.PTO

322782 U.S.PTO
60/545161
021804

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53 (c).

INVENTOR(S)		
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☐ *Additional inventors are being named on the _____ separately numbered sheets attached hereto*

TITLE OF THE INVENTION (280 characters max)

STRIP EJECTION SYSTEM

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PATENT TRADEMARK OFFICE

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☒ Specification *Number of Pages* 5 ☐ CD(s), Number

☒ Drawing(s) *Number of Sheets* 3 ☐ Other (specify)

☒ Application Data Sheet. See 37 CFR 1.76

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT *(check one)*

☐ Applicant claims small entity status. See 37 CFR 1.27.

☒ A check or money order is enclosed to cover the filing fees

FILING FEE AMOUNT ($)

☒ The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 22-0261 160.00

☐ Payment by credit card. Form PTO-2038 is attached.

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____.

Respectfully submitted,

SIGNATURE John P. Shannon Date 2/18/04

TYPED or PRINTED NAME John P. Shannon REGISTRATION NO. *(if appropriate)* 29,276

TELEPHONE 202-344-4000 Docket Number: 39348-200945

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51, and is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. SEND TO: Box Provisional Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

VENABLE
ATTORNEYS AT LAW

INVENTORS:

Signed:_____ Date:_____

Name:_____

Signed:_____ Date:_____

Name:_____

Signed:_____ Date:_____

Name:_____

Signed:_____ Date:_____

Name:_____

DC2DOCS1/523851

INVENTION DISCLOSURE

INVENTION TITLE: Strip Ejection System

INVENTORS: Garry Chambers, Alastair Hodges and David Sayer

SUMMARY OF INVENTION:

In devices where a disposable element is to be located in a non-disposable element and the disposable element used and then disposed of, it is often desirable to minimise contact between an operator and the used disposable element. This is particularly so for devices where blood or other potentially infectious agents are present in or on the disposable element. An example of such a device is a strip and meter based testing device for medical use. In this type of device a disposable strip or other shaped element is filled with a biological sample such as blood, either while located or prior to being located in a meter that reads the test result. The present invention is a simple to implement and robust system for incorporation into the non-disposable element that allows the operator to transport the disposable element within or out of the non-disposable element without having to contact the disposable element. In the case of transporting the disposable element out of the non-disposable element the current invention functions as an ejection mechanism. In the case of transporting the disposable element within the non-disposable element the present invention functions to transport the disposable element to its position for use from an internal or external storage position. One or both of these functions can be performed by the present invention. The present invention will be described with reference to a disposable strip and meter based sensor device but it is to be understood that it is applicable to any device where it is desirable to be able to eject a disposable element from a non-disposable element with no direct operator contact to the disposable element.

DETAILS OF INVENTION:

Ejection systems for disposable strips in strip and meter based sensor systems are known. The blood glucose monitor marketed by Bayer Diagnostics under the name Glucometer ESPRIT™ in Australia and Ascensia™ DEX® 2 in the USA transports the used strips via the movement of a set of levers and springs activated by the user sliding a pad on the face of a meter. This mechanism transports the strip from a cassette in the meter to the test position then ejects the strip after use. This is a relatively complicated system requiring multiple moving parts and is thus subject to mechanical failure. It also pushes the strip from the end so has to be designed not to interfere with the electrical connection pins to the strip. Devices according to the present invention seeks to overcome these deficiencies in the prior art by providing a simple system that can have only a single moving part, that is robust, easy to implement and can operate on a portion of the strip removed from the area of the electrical connection pins. It will be described with reference to a substantially flat strip shaped disposable element that is inserted into a port in the meter, however it is equally applicable to disposable elements with other shapes and non-disposable devices with functions other than metering.

The device consists of a pressing means such as a cylinder, ball or plate that is pressed down against a face of the strip and moved to transport the strip into position in the meter port for a test to be performed, out of the meter port after a test has been performed, or both. In this disclosure a strip face is taken to be an area of the strip that extends in the directions parallel to the direction in which the strip is to be transported. Examples of such areas are the large area faces of the strip that, with the strip laid flat would form the upper and lower faces of the strip or the smaller area faces that, with the strip laid flat would form the side edges of the strip. In operation the pressing means is pressed against a face of the strip by the operator to make contact with the strip. The pressing means is then moved by the operator, while maintaining contact with the strip, such that the strip is transported into or out of the meter port by the operator movement. The pressing means is to be capable of a wide enough range of movement such that the strip can be transported to a position where it can be correctly located in the strip port to perform a test in the case of transporting the strip to the meter port or removed from the meter under gravity in the case of moving the strip out of the strip port. After the strip is moved to such a position by the pressing means the operator pressure on the pressing means is removed, either leaving the strip ready to perform a test in the case of transport to the meter port or freeing the strip and allowing it to fall away from the meter under gravity in the case of transporting the strip out of the meter port. In the latter case the operator could be instructed for example, to hold the meter plus strip over a waste receptacle when ejecting the strip, such that when the strip fell it was received by the waste receptacle.

In a preferred embodiment of the present invention the pressing means is a cylinder mounted on an axle that is located in the case of the meter. The cylinder would be mounted such that it could be pressed down against a face of the strip and rotated relative to the meter case. The rotation could be achieved by allowing the cylinder to rotate relative to the axle, or more preferably by allowing the axle to rotate relative to the meter case. In a particularly preferred embodiment the axle would have sufficient movement within the holes or indentations in which the axle ends locate in the meter

case to allow the cylinder to be pressed and move down to contact the strip face. The strip can be transported by the operator pressing on the cylinder and rotating it, so that the cylinder contacts the strip and simultaneously transports it in the direction of rotation. To be able to do this, when pressed against the face of the strip, the contact force between the cylinder and the face of the strip must be high enough relative to the forces holding the strip in the meter port to allow the strip to be moved by rotating the cylinder.

In a preferred embodiment the surface of the pressing means contacting the strip would be made of material with a suitable frictional coefficient such that the strip could be moved by the pressing means when the latter was moved without requiring excessive pressing force. Examples of such material are polymers such as elastomers. Suitable elastomers include natural rubbers, synthetic rubbers, silicone rubbers and mixtures thereof. In a particularly preferred embodiment the material would be Thermoflex® (Plastic Technologies Service, Adelshofen, Germany)

This system has several advantages over the prior art.

It is simple. Essentially only one part is required to implement the device.

It is robust to mechanical failure. There is no requirement for springs or fragile parts that could fail with repeated use and it is possible for all parts to be made by inexpensive plastic moulding operations.

The applied force can be easily regulated by the operator. Unlike systems with springs and levers the direct nature of this device allows the operator to easily feel and apply the correct pressing and rotating or sliding force to successfully transport the strip.

It is robust to transport failure. With more complicated mechanisms it is not always easy to reset and reapply the transport mechanism if it failed to work properly in the first instance. With the present invention however it is a simple matter for the user to either carry on rotating the transport cylinder or remove the pressing force and slide back a pressing pad to re-contact the strip at a further point and ensure proper transport.

Since the present invention can work by applying a pressing force to a face of the strip it is not necessary for the transport mechanism to act on the end edge of the strip located in the meter port. In strips where electrical connection between the meter and the strip is required it is desirable to have the connections adjacent to the end of the strip inserted into the meter. This is desirable for cost reasons as it allows for a smaller area of strip to be located in the meter and therefore a smaller overall strip size to be used. It is also desirable for ergonomic and user recognition reasons where the user can clearly identify the connection area at the end of the strip in the case where the user inserts the strip into the meter.

Transport systems according to the prior art act by pushing against the end edge of the strip. Since for the reasons given above the electrical connection pins are also often in this region a design problem is presented where the connection pins and the transport pushing means need to be both fitted into a small area. In particular the pushing means would be required to fit under or penetrate through the connection pin area,

typically requiring small parts which could be fragile and difficult to handle in assembly during manufacture. A transport system according to the current invention obviates this need by allowing the pressing means to be pressed against a flat face of the strip. This can be removed from the area of the electrical connection pins. It can be adjacent to or overlie the area occupied by the pins without interference or the necessity of using small parts as it can be located on a face of the strip opposite to that on which the pins sit or, in the case of edge faces it can sit adjacent to the pins with an axis of movement perpendicular to the plane of the connector pins. It can also sit just in front of the pins on any face of the strip.

In another embodiment of the current invention a ball on an axle is used rather than a cylinder. This may have advantages in reducing the amount of space required by the device and also may allow the operator to more easily apply a greater pressure to the strip as the area of the wheel that contacts the strip will in most cases be smaller than for a cylinder of corresponding size. With a smaller contact area a greater pressure can be applied by the same force.

In yet another embodiment of the current invention a sliding pad is used rather than a rotating cylinder or ball. In this embodiment the operator would apply pressure to the pad to contact the strip and then slide the pad in the direction that the strip is to be transported. To reset the mechanism the pad could be retracted by the operator manually or the pad could be automatically retracted when a new strip is to be located in the meter port.

Embodiments of the current invention are given in figures 1 to 6. In these figures the strip is shown in its test position, from which point it can be ejected. In the case of transporting the strip to the meter port the pressing means would be located to initially contact the strip near the end of the strip opposite to the electrical connection end, and the pressing means used to transport the strip such that the electrical connection end of the strip was aligned with the meter connection area at the end of the transport process. In this case the strip may need to be presented to the transport mechanism from its storage position by a separate device.

Figure 1 shows a schematic illustration of a cylinder embodiment of the current invention.

Figure 2 shows a cross-section of the cylinder embodiment of the current invention where the section is taken parallel to the ejection direction of the strip.

Figure 3 shows a cross-section of a ball embodiment of the current invention where the section is taken perpendicular to the ejection direction of the strip.

Figure 4 is a top view of a plate embodiment of the current invention.

Figure 5 is a cross-section of a plate embodiment of the current invention where the section is taken parallel to the ejection direction of the strip. The plate is shown in its retracted position.

Figure 6 is the same section as shown in figure 5 except with the plate shown in its extended pushing position.

The figures will now be discussed in some detail. In figure 1 a substantially flat rectangular strip 1 is inserted into a port in meter casing 4. A cylinder 2 is positioned above 1 such that it can be pressed against the upper face of the strip by an operator. Further, the cylinder is mounted on an axle which extends into the collar 3, such that the cylinder can be rotated by a operator to eject the strip from the port.

Figure 2 shows a cross-section of the device shown in figure 1. The numbered elements in figure 2 correspond to the same numbered elements in figure 1. In addition the axle 5 upon which the cylinder is mounted can be seen. The curved arrow labelled 6 shows the direction of rotation that would be imparted by an operator to eject the strip 1 from the meter port. A connector pin 7 for the meter to make electrical connection to the strip is shown in a typical position.

Figure 3 shows a cross-section of a ball embodiment of the current invention viewed from the front. According to this embodiment a raised section 20 of the ball 70 can be pressed against the disposable element 10. The reduced area of contact between the pressing means and the disposable element compared to the cylinder embodiment means that a higher pressure can be applied by the operator for the same force.

Figures 4, 5 and 6 show aspects of a pad pressing means embodiment. In this embodiment a pad 200 made of a soft material such as natural rubber is mounted in a plate body 700, which in turn is mounted to the case 400. The pad is shaped to have a protrusion 800 which can be brought into contact with the disposable element 100 in order to transport it out of the port to eject it. The plate body 700 has a barb 600 formed at its innermost end. This barb has a dual purpose. It serves to retain the plate body to the case when the plate body is in its fully extended position, as shown in figure 6 and it acts against the protrusion 500 to lift 800 away from the disposable element 100 when 700 is in its fully retracted position, as shown in figure 5. The plate body 700 is mounted to the case 400 by pins 900 located in slots 1000, such that the pins can move along the slot to advance and retract the plate. An electrical connection pin 1100 is shown in a typical position in figures 5 and 6.

In another embodiment of the present invention the transport mechanisms disclosed could be moved by a motorised assembly rather than by the operator directly. This has advantages in requiring less intervention by the operator but has increased complexity when compared to the preferred embodiment.

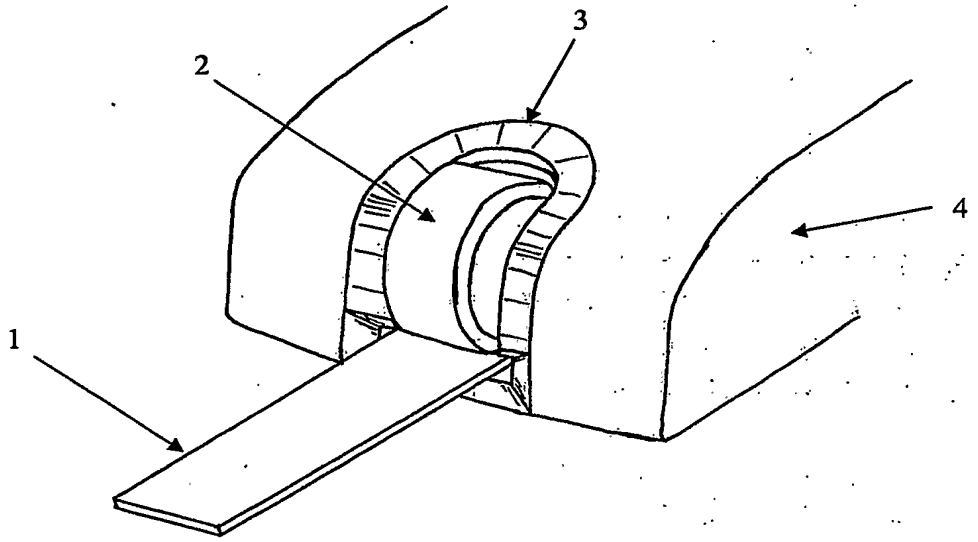

Figure 1

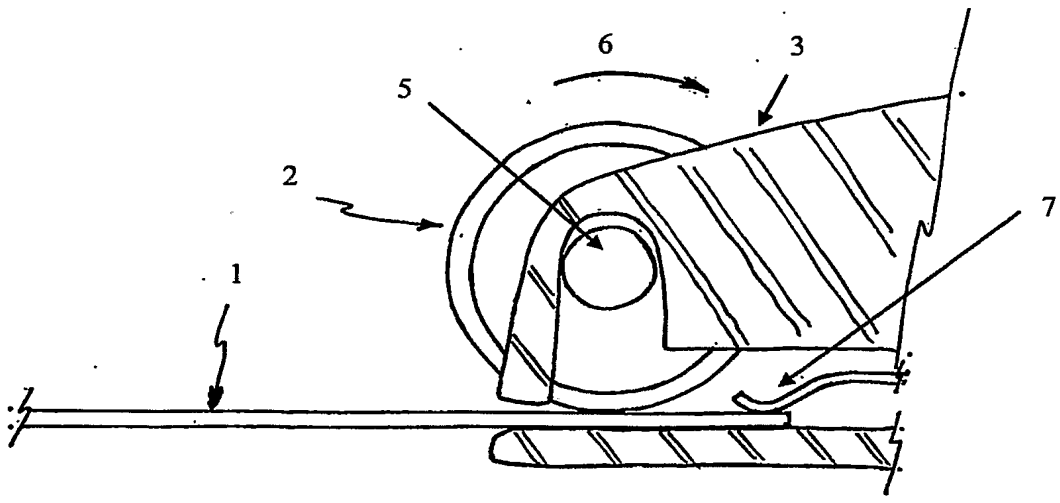

Figure 2

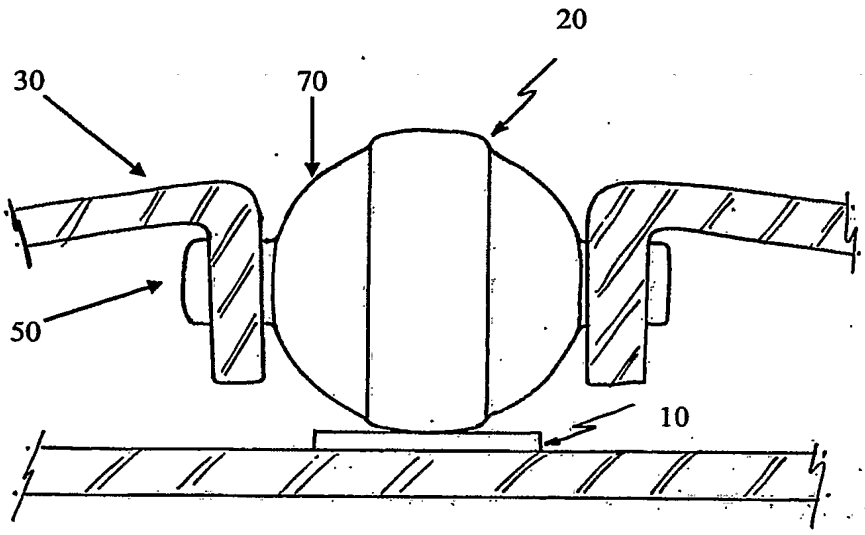

Figure 3

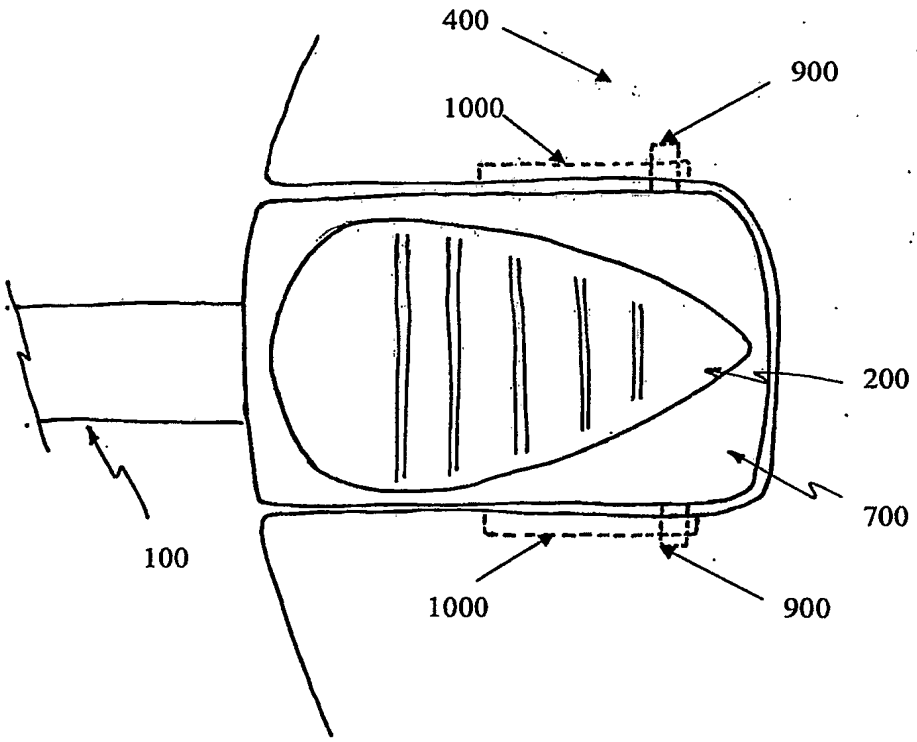

Figure 4

APPLICATION DATA SHEET

Application Information

Application Number::	To Be Assigned
Filing Date::	February 18, 2004
Application Type::	Provisional
Subject Matter::	Utility
Title::	STRIP EJECTION SYSTEM
Attorney Docket Number::	39348-200945
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Request for Non-Publication?::	No
Suggested Drawing Figure::	Figure 1
Total Drawing Sheets::	3
Small Entity?::	NO

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